

Remarks

Reconsideration of this Application is respectfully requested.

Applicants wish to thank Examiner Kruse for the telephonic interview on June 18, 2004. Further to this conversation, Applicants have changed the status identifier of claim 12 from "not entered" to "new". It is Applicants' understanding that claim 12, now properly designated, will be entered.

Upon entry of the foregoing amendment, claims 1, 2, 4-6, 8, 9, and 11-29 are pending in the application, with claims 1, 12, 14, and 21 being the independent claims. Claims 3 and 7 were previously cancelled. Applicants again request that claim 12 be entered. Claim 10 is sought to be cancelled without prejudice to or disclaimer of the subject matter therein. New claims 12-29 are sought to be added. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Claims Copied From Issued Patent

Under 37 C.F.R. § 1.607(c), claims 14-29 are copied from U.S. Patent No. 6,521,458 (the '458 patent), issued February 18, 2003. Claims 14-29 correspond to claims 1-16 of the issued patent. According to its face page, the earliest priority date of the '458 patent is May 22, 1998. The captioned application claims priority to EP 97201990.1 filed June 30, 1997.

Support for the new claims is found throughout the specification and in the originally filed claims. For example, page 3, lines 5-7 of the specification state: "[a]lso part of the invention is a method for obtaining transgenic plants which do not contain vector sequences outside the T-DNA by transforming plants with a vector according to the invention."

In addition, the specification discloses that:

This [plant] transformation procedure [using *Agrobacterium*] generally consists of infection of plants with non-tumorigenic *Agrobacterium* strains which have been provided with a heterologous gene. This heterologous gene is located on a plasmid in a piece of so-called T-DNA, which is the DNA located between two imperfect direct repeats of about 24 basepairs length, the T-DNA borders.

See the specification at page 1, lines 16-22.

In addition, the specification states that "[o]ne embodiment of the invention comprises a vector in which a gene coding for a toxin under the control of a plant-expressible promoter is located outside the T-DNA borders." See the specification at page 4, lines 21-23. Additionally, Examples 1-5 of the application describe inserting, for example, a barnase cassette next to (i.e., beyond) the left border. See the specification at page 12, line 40.

Furthermore, the specification describes methods of plant transformation that "can be done by ... insert[ing] a coding sequence outside the T-borders which, whether or not in cooperation with genes from the host plant or genes cotransferred, are toxic to plants so that there is counterselection for plants with superfluous vector-DNA."

Abstract.

Moreover, page 10, lines 4-20 of the specification, describe methods of regenerating plants from transformed plant cells.

Further support for the new claims is as follows:

The invention comprises a vector for plant transformation comprising a T-DNA with flanking T-DNA borders, characterized in that the vector further comprises a nucleic acid sequence which prevents the development of plant transformants having more vector sequences than the T-DNA sequence.

See specification at page 2, lines 28-29.

New Claim 12 Must be Entered

It is respectfully requested that claim 12 be entered upon receipt of this Amendment and Reply. Claim 12 is the claim presented for copying by the Office in the Office Action mailed March 28, 2001. If the Office believes that this subject matter is unpatentable to Applicants, entry of the claim, and a subsequent *rejection* is appropriate. MPEP § 2305.02 ("Where claims are suggested for interference, a limited period determined by the examiner, not less than one month, is set for reply ... Should any one of the applicants fail to present the claim or claims suggested within the time specified, all claims not patentable thereover are rejected on the ground that the applicant has disclaimed the invention to which they are directed. *If the applicant presents the suggested claims later they will be rejected on the same ground.*" (emphasis added)).

Likewise, MPEP § 2305.02 states: "[c]laims may be *rejected* on the ground that applicant has disclaimed the subject matter involved ... [t]he rejection on disclaimer applies to ... the claims directly involved." (emphasis added).

Furthermore, whether the subject matter of claim 12 is disclaimed is appealable, according to the decision on the renewed petition under 37 C.F.R. § 1.605 mailed on July 17, 2002 ("Decision"): "[t]he questions of whether or not claims are patentable or have been disclaimed relate to the merits of the invention, and the appropriate remedy for resolution of these issues ultimately lies by appeal ..." Decision at page 1. *See also* MPEP § 2307.02 ("The penalty under 37 C.F.R. § 1.607(b) is loss of the claim or claims

involved, on the doctrine of disclaimer, and this is appealable ..."). Accordingly, claim 12 must be entered in order to put the application in condition for appeal.

Based on the above amendment and the following remarks, Applicant respectfully requests that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Objections to the Claims

The objections to claim 2 as allegedly containing informalities are rendered moot by the above amendment to claim 2 and the addition of new claim 13. Specifically, the objection to claim 2 as needing "and"-delineators for separating the species is rendered moot by the cancellation of the second species set, which has been listed in new dependent claim 13. Moreover, the term "and" after "a protease" sufficiently delineates the Markush group of genes encoding a toxin gene as all of the genes listed are toxin genes, including a gene coding for an antisense sequence for a housekeeping gene as such a gene is toxic to the plant. The duplicate recitation of "dicarboxylate translocator gene" at line 6 of the claim 2 has been deleted. Withdrawal of the objections to claim 2 is therefore respectfully requested.

The objection to claim 10 as allegedly being of improper form is also rendered moot by the cancellation of this claim. Withdrawal of this objection is therefore respectfully requested.

The objection to claim 5 as failing to comply with 37 C.F.R. § 1.821(c) has been overcome by the insertion of a sequence identifier. Withdrawal of this objection is therefore respectfully requested.

Objections to the Drawings

The objection to the drawings by the Draftsperson is traversed by the filing of formal drawings herewith.

Rejections under 35 U.S.C. § 112

Written Description Rejection

The rejection of claims 1, 4, 6 and 8-11 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement is respectfully traversed.

Specifically, the claimed subject matter is described in the specification in such a way as to reasonably convey that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully disagree with the assertion in the Office Action that the "Applicant does not describe the genus of genes encoding a toxin or nucleotide sequences that interfere with DNA unwinding required to make a vector and practice the methods as broadly claimed." Office Action at page 4-5. In fact, the opposite is true because the specification sets forth a comprehensive list of toxins, for example, at page 2, lines 35-39 as well as examples of suitable nucleotide sequences at, for example, page 8, line 4 to page 9 line 3.

Moreover, it is irrelevant that the specific sequence of each toxin or each nucleotide sequence that interferes with DNA unwinding is not listed as such specificity is not necessary to fulfill the written description requirement. As stated in *In re Hershchler*, 591 F.2d 693, 697, 200 USPQ 711, 714 (CCPA 1979), cited in MPEP § 2163, "the use of known chemical compounds in a manner auxiliary to the invention must have a corresponding written description only so specific as to lead one having

ordinary skill in the art to that class of compounds." Accordingly, the above-identified portions of the specification provides a written description specific enough to lead one of ordinary skill in the art to a class of toxin genes and nucleotide sequences that interfere with DNA unwinding.

The allegation in the Office Action that there is no described or art-recognized correlation or relationship between the structure of the claimed invention and its function is also erroneous. The structure of the vectors of the claimed invention are clearly related to their function. As described in the specification, the structure of the vectors of the claimed invention eliminates the problem of plant transformants that have more vector sequence other than the T-DNA sequence. For example, the specification states: "[t]he invention comprises a vector for plant transformation comprising a T-DNA ... characterized in that the vector further comprises a nucleic acid sequence which prevents the development of plant transformants having more vector sequences than the T-DNA sequence." *See* specification at page 2, lines 28-32. Therefore, the structure of the vector is correlated to its function.

Claim 1, for example, is directed to a *vector* and the structure of the vector is adequately described in the claim and throughout the specification. For example, both Figures 1 and 2 adequately describe representative constructs that may be used in the practice of the claimed invention. Further, the specification states that "all known plasmids and vectors" can be adapted for use in the methods of the present invention, and many such plasmids are listed. *See* specification at page 3, lines 26-28.

Each of claims 4, 6, 8-11 depends from claim 1 as follows: claims 4 and 6 are directed to a vector according to claim 1, claim 8 is directed to a method for obtaining a

transgenic plant comprising transforming a plant cell with the claimed vectors, claims 9-10 are directed to a plant host comprising the claimed vectors and claim 11 is directed to a method of transforming plant cells with the claimed vector. For the reasons outlined above, each of these claims also has adequate written description.

Enablement Rejection

The rejection of claims 1, 2, 4, 5, 6 and 8-11 under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims is respectfully traversed.

One of reasonable skill in the art could make or use the presently claimed invention without undue experimentation. The test for enablement is "whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."

United States v. Telectronics, Inc., 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988).

Factors to be considered when determining whether a claim is sufficiently enabled by the specification and whether any experimentation is "undue" include, but are not limited to: (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one or ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. MPEP § 2163.

Breadth of the Claims

One of skill in the art is enabled to make and use the claimed invention throughout its entire scope without undue experimentation. The determination of the propriety of a rejection based upon the scope of a claim relative to the scope of the enablement involves two stages of inquiry. The first is to determine how broad the claim is with respect to the disclosure. The entire claim must be considered. The second inquiry is to determine if one skilled in the art is enabled to make and use the entire scope of the claimed invention without undue experimentation. MPEP § 2164.08. How a teaching is set forth, by specific example or broad terminology, is not important. *In re Marzocchi*, 439 F.2d 220, 223-4 169 USPQ 367, 370 (CCPA 1971).

Claim 1 is directed to a vector for plant transformation comprising a T-DNA sequence, the T-DNA sequence comprising a sequence located between two direct repeats, and a gene encoding a toxin gene and/or a nucleotide sequence that interferes with DNA unwinding, wherein said gene encoding a toxin sequence and/or a nucleotide sequence that interferes with DNA unwinding is not located within said T-DNA sequence.

To enable the claimed invention it is not necessary to list in the specification each toxin gene and/or each nucleotide sequence that interferes with DNA unwinding because such information is readily available to one of skill in the art. *See* MPEP § 2164.01. "A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner* 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991) ...")

As noted in the specification, the transformation of plants using, for example, *Agrobacterium*, has been known since 1983. *See* specification at page 1, lines 14-16.

This transformation procedure generally consists of infection of plants with non-tumorigenic *Agrobacterium* strains containing a heterologous gene. The heterologous gene is typically located on a plasmid in a piece of T-DNA. As of the filing date of the above-identified Application, vectors for plant transformation comprising a T-DNA sequence had been used for over almost 15 years.

Moreover, as stated in the specification, "[b]asically all known plasmids and vectors which are used for plant transformation can be adapted to a vector according to the invention or a vector usable in a method according to the invention." *See* specification at page 3, lines 26-28. The specification then describes the characteristics of the plasmids used in the invention, i.e., that they contain T-DNA flanked by T-DNA border sequences. *See* specification at page 3, lines 33-34. The specification also describes in general, and, in particular, how to make the vectors of the present invention. *See*, for example, the specification at page 4, lines 5-19, Figures 1 and 2 and the Examples. Because one of skill in the art is enabled to make and use the claims of the present invention without undue experimentation, the claims are fully enabled.

The Nature of the Invention, State of the Prior Art and Level of Skill in the Art

The subject matter of the claimed invention includes, but is not limited to, plant molecular biology. The state of the prior art was sophisticated. For example, as discussed above, the transformation of plants using *Agrobacterium* had been known since 1983. Moreover, many types of plants could be regenerated from cultured cells or tissue and after the stable incorporation of heterologous gene sequences into such regenerable plant cells, the traits conferred by them could be transferred to the progeny of plants regenerated from these cells. The skill of artisans in this field was also high,

and such artisans typically include individuals with Ph.D.'s in plant molecular biology. Because both the state of the prior art and level of skill in the art was high at the time the application was filed, this factor also demonstrates that the claims are enabled.

The Level of Predictability in the Art

Even assuming, *arguendo*, that there is some unpredictability in plant molecular biology, any experimentation that may be necessary to practice the present invention would not be unreasonable because, as discussed above, the techniques of making and using plant transformation vectors were well known in the art.

The Amount of Direction Provided by the Inventor and The Existence of Working Examples

The present application contains nine working examples detailing the creation of five vector constructs. Potato stem segments were then transformed with each of these constructs. *See* Example 6. These working examples combined with the general knowledge of those skilled in the art as evidenced in, for example, J. Sambrook, E. F. Fritsch and T. Maniatis (1989) *Molecular Cloning – A Laboratory Manual*, Cold Spring Harbor Laboratory Press, demonstrate that the invention is fully enabled.

The Quantity of Experimentation Needed to Make or Use the Invention Based on the Content of the Disclosure

As discussed above with respect to the other factors, any experimentation that may be needed to practice the full breadth of the claims would not be unreasonable. There is ample support both in the application itself and in the literature guiding the skilled artisan on genetic manipulation techniques to make and use the vectors and plant hosts of the present invention. The application provides nine working examples which

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provide sufficient guidance to one of ordinary skill in the art as to how to make and use the present invention.

For all of the reasons outlined above, withdrawal of this rejection is respectfully requested.

Indefiniteness Rejection

The rejection of claims 1, 2, 4, 5, 6 and 8-11 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant allegedly regards as the invention is respectfully traversed.

Applicants respectfully disagree with the allegation that the metes and bounds of claim 1 are unclear. However, solely to expedite prosecution, claim 1 has been amended to state that the gene encoding a toxin sequence and/or a nucleotide sequence that interferes with DNA unwinding is not located within said T-DNA sequence. This amendment to claim 1 should not be taken as acquiescence to the Office's rejection.

Claim 1 and its dependent claims 2, 4-6 and 8-11 are definite. Accordingly, withdrawal of this rejection is therefore respectfully requested.

Claim 11 has been amended to read "a transformed plant cell" and not "the transformed plant cell." Withdrawal of this rejection is therefore respectfully requested.

Rejections under 35 U.S.C. § 102

The rejection of claims 1, 2, 8 and 11 under 35 U.S.C. § 102(g) as anticipated by Gutterson *et al.*, U.S. Patent No. 6,521,458 ("Gutterson") is respectfully traversed.

The basis for the rejection under 102(g) is that the alleged failure to copy the claim set forth in the Office Action mailed March 28, 2001 constituted an alleged

disclaimer of the subject matter in that claim. OA at page 8. The Office Action cites *In re Oguie*, 517 F.2d 1382, 186 USPQ 227 (CCPA) in support of the contention that this alleged disclaimer amounts to a concession that, as a matter of law, the patentee is the first inventor in this country.

As discussed in more detail below, the Applicants in no way disclaimed the subject matter of the claim presented by the Examiner for copying and in no way conceded that the patentee was the first to invent the subject matter set forth in the claim presented to be copied.

However, even assuming, *arguendo*, that the Applicants are found to have disclaimed the subject matter contained in the claim suggested by the Office, claims 1, 2, 8 and 11 are not anticipated by Gutterson. Even if it is found that Gutterson invented the species listed in the suggested claim prior to Applicants inventing that species, there is no evidence that Gutterson invented the genus or any other species prior to the Applicants. In other words, the Office has not established that the species set forth in the suggested claim actually anticipates claims 1, 2, 8 and 11 (i.e., actually was invented prior to the invention set forth in those claims).

Again, even assuming that Applicants are found to have disclaimed the subject matter of the suggested claim, and thus allegedly have conceded that, as a matter of law, the patentee is the first inventor in this country of the subject matter *of that claim*, Applicants are not presumed to have conceded prior inventorship of any other subject matter. The following quotation from *In re Oguie* is on point:

In *Embree* the applicants refused to copy a suggested claim to a species apparently within a genus already claimed in their application. The Board of Appeals held, on the authority of *Ethyl Gasoline*, that the subject matter of the suggested claim could not be used as prior art ... In *Lyon v.*

Boh, supra, cited by the board as additional authority, the court found that an applicant's failure to copy claims ... resulted in a disclaimer only of the particular species defined by the suggested claims. Neither *Embree* nor Lyon is *aposite* to this case.

In re Ogiue, 517 F.2d 1382, 1392.

The relative filing dates of the above-identified application and Gutterson are also relevant to the analysis. Gutterson was filed on April 30, 1999, claiming priority to a provisional application filed on May 22, 1998. The above-identified application was filed internationally on June 29, 1998, claiming priority to EP 97201990.1 filed June 30, 1997. Thus, Gutterson is not prior art to the captioned application, and there is no evidence to support that Gutterson invented, for example, claims 1, 2, 8 and 11 prior to the above-named inventors. In fact, the relative filing dates suggests just the opposite.

Additionally, in supporting its anticipation rejection, the Office improperly relied on the whole of Gutterson's teachings. The Office has not demonstrated that the "reference," i.e., the claim presented for copying, contains each and every element of claims 1, 2, 8 and 11. To anticipate a claim, the reference must teach each and every element of the claim. See *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The Office is permitted only to use the disclosure to define the subject matter of the suggested claim:

In determining that the subject matter of Iwata claims 1-5 is effectively prior art to appellant, we are not agreeing with the board that 'all of the subject matter in Iwata *et al.* necessary to support the claims is available to us as reference material.' Appellant has made no concession and is subject to no disclaimer with respect to the disclosure of Iwata. The disclosure is available only to determine what invention the claims define and hence what invention has been disclaimed so as to be available as prior art.

In re Ogiue, 517 F.2d 1382, 1391. Likewise, in the present instance the only subject matter available as a "reference" to the present claims is the material defined in the claim presented for copying.

Specifically, claims 1 and 2 are directed to a vector and the claim presented for copying was drawn to a method for producing a transgenic plant. Likewise, claims 8 and 11 are directed to a method for obtaining a transgenic plant comprising transforming a plant cell with the vector of claim 1, 2, 4, 5 or 6, selecting a transformed cell, and producing a plant from the transformed cell and to a method for the transformation of plants comprising transforming a plant cell with the vector of claim 1, 2, 4, 5 or 6 and selecting the transformed cell. The reference material (i.e., the suggested claim) discloses only a method for producing a transgenic plant containing a polynucleotide of interest, the method comprising introducing into a plurality of plant cells a T-DNA vector comprising: a T-DNA sequence comprising a right border, a left border and the polynucleotide of interest positioned between the right border and left border, and a non-T-DNA sequence comprising a barnase polynucleotide sequence encoding a barnase enzyme, wherein said non-T-DNA sequence is located beyond the left T-DNA border; selecting a plant cell which comprises the T-DNA sequence and does not comprise the toxin polynucleotide sequence; and regenerating a transgenic plant from the selected plant cell. This reference therefore does not disclose each and every limitation of the claims.

Withdrawal of this rejection is therefore respectfully requested.

As discussed above, Applicants do not concede that the subject matter presented in the suggested claim was disclaimed. For example, a claim was already pending in the

application at the time the proposed claim was filed that encompassed the subject matter in the suggested claim. Therefore, the suggestion of a claim to the applicant by the Office under 37 C.F.R. § 1.605 was inappropriate.

In addition, the facts of *In re Oguie*, cited by the Office, are distinguished from the facts of the present case. In *In re Oguie*, the Applicants refused to copy the claim. In the present case, as discussed above, a relevant claim was already pending in the application. In addition, Applicants did not *refuse* to copy the claim verbatim but, rather, did not copy the claim verbatim because of extraordinary circumstances that were beyond Applicants' control. For example, the deadline for copying the claim was buried within the Office Action and the buried deadline contradicted the deadline on the face of the Office Action. At the same time, Applicants were in the middle of transferring files to another law firm when the Office Action was mailed. This resulted in a delay in the Office Action getting to the appropriate party to prepare a response. The delay, however, was within the three month deadline on the face of the Office Action thus leading Applicants and their representatives to believe that there was sufficient time to review the Office Action and respond in a timely manner.

Rejections under 35 U.S.C. § 103

The rejection of claims 1, 2 and 8-11 under 35 U.S.C. § 103 as allegedly being unpatentable over Gutterson is respectfully traversed.

For the reasons outlined above, Gutterson does not render claims 1, 2 and 8-11 obvious. The Office improperly relied on the whole of Gutterson's teachings to support the obviousness rejection, e.g., at page 10 of the Office Action, Example 4 is cited to support the rejection. As discussed above, reliance on the entire teaching of Gutterson is

improper. Moreover, the Office has not established why any subject matter other than that set forth in the claim presented for copying is prior art to the above-identified application. Reconsideration and withdrawal of this rejection are therefore respectfully requested.

The rejection of claims 1, 4, 5, and 9-11 under 35 U.S.C. § 103 as allegedly being unpatentable over Ramanathan *et al.*, *Plant Molecular Biology* 28:1149-1154 (1995) ("Ramanathan") in view of D'Souza-Ault *et al.*, *J. Bacteriology* 175:3486-3490 (1993) ("D'Souza-Ault") is respectfully traversed.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, the prior art reference, or references when combined, must teach or suggest all the claim limitations. Second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Last, there must be a reasonable expectation of success of practicing all of the claim limitations. MPEP § 2143.

Neither Ramanathan nor D'Souza-Ault, neither individually nor in combination, teach or suggest a vector for plant transformation comprising a T-DNA sequence, the T-DNA sequence comprising a sequence located between two direct repeats, and a gene encoding a toxin gene and/or a nucleotide sequence that interferes with DNA unwinding, or methods of using such a vector. Ramanathan teaches only that "it would be desirable to incorporate into a [sic] T-DNA vectors a 'stop-transfer' signal adjacent to the left border." OA at page 10. Ramanathan does not teach or even suggest including a toxin

gene and/or a nucleotide sequence that interferes with DNA unwinding in a plant transformation vector.

D'Souza-Ault does not cure the deficiencies of Ramanathan. D'Souza-Ault is a bacteriology reference that describes the identification of a specific Ros binding sequence in the promoter region of the *virC* and *virD* operons of *Agrobacterium*. D'Souza-Ault is silent regarding vectors for plant transformation, and methods for their use. Therefore, neither Ramanathan nor D'Souza-Ault, neither individually nor in combination, teach the vectors or methods of the present invention.

There is also no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify either of the references or to combine the reference teachings. There is no suggestion or motivation in either Ramanathan or D'Souza-Ault to combine these references to arrive at the claimed invention.

Lastly, because the references, either alone or in combination, do not teach the claimed invention, there can be no reasonable expectation of success of practicing the combined teachings of the references to arrive at the claimed invention.

Conclusion

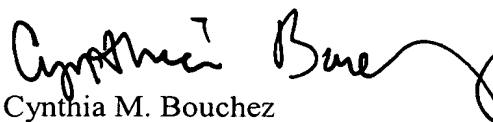
All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will

expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read "Cynthia M. Bouchez", written over the printed name.

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